

**Toronto Academic Health Sciences Network (TAHSN)  
HUMAN SUBJECTS RESEARCH APPLICATION**

All sections of this application **MUST** be completed before it will be considered for REB review. A complete application must be submitted to each site where this research will take place. A separate detailed protocol must be included with each application. See TAHSN Guidelines for Research Ethics Review Involving Human Subjects.

<b>SECTION I: GENERAL INFORMATION</b>
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**1. PRINCIPAL INVESTIGATOR NAME\***

\* If your institution requires the PI to be a staff member, the on-staff investigator accepts the role and responsibilities of PI at this institution.

Title (e.g. Dr.):	Last Name:	First Name:
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**2. FULL STUDY TITLE**

Sponsor Protocol Number (if applicable):

**2A. Is this protocol directly related to a previously approved study at this institution (e.g., extension, rollover, subsequent to a pilot study)?**  Yes  No

If Yes, indicate name of Principal Investigator:                      and REB file number:

**3. SOURCE OF FUNDING**

Sponsor Name:		
Granting Agency Name:		
Internal Funding:		
Other:		
<input type="checkbox"/> Funding obtained		
<input type="checkbox"/> Funding applied for	Expected date of decision:	
<input type="checkbox"/> No funding required	Explain:	

**4. INVESTIGATORS****4A. PRINCIPAL INVESTIGATOR CONTACT INFORMATION AND SIGNATURE**

**PRINCIPAL INVESTIGATOR AGREEMENT** – I assume full responsibility for the scientific and ethical conduct of the study as described in this application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects and any other relevant regulations or guidelines. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this project.

Dept/Div:	Program:	Institution:
Telephone:	Pager:	Fax:
Street Address:		
City:	Province:	Email:
Signature of Principal Investigator		Date

**4B. CO-INVESTGATOR(S) CONTACT INFORMATION AND SIGNATURE**

**CO- INVESTIGATOR AGREEMENT** – I agree to participate in this study as described in this application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects and any other relevant regulations or guidelines.

1	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
2	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
3	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
4	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
5	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	

**4C. CONTACT PERSON FOR THIS APPLICATION IF NOT THE PRINCIPAL INVESTIGATOR (e.g. study coordinator, research administrative contact, research student, institutional liaison).**

Not Applicable

**Contact's Role in Study:**

Indicate to whom correspondence should be mailed:  PI  Other

Title:	Last Name:	First Name:
Dept/Div:	Program:	Institution:
Telephone:	Pager:	Fax:
Street Address:		
City:	Province:	Email:

**5. DEPARTMENT/DIVISION/PROGRAM APPROVAL \***

\* For institutions that require the PI to be a staff member, approval must come from the Department / Division / Program Head of the same institution as the PI.

**DEPARTMENT/DIVISION/PROGRAM HEAD APPROVAL** – I am aware of this proposal and support its submission for ethics review. I consider it to be feasible and appropriate. I attest that the Principal Investigator responsible for the conduct of this study is qualified by education, training, and experience to perform his/her role in this study.

Title:	Last Name:	First Name:
Signature of Dept/Div/Program Head		Date

**6. STUDY PERIOD**

**Expected start date:**                      **Total study duration:**

**7. OTHER ETHICS/SCIENTIFIC/SCHOLARLY REVIEW**

In order to facilitate the REB review process through harmonization and coordination of REB activity, identify if any of the REBs below have reviewed and/or approved the study outlined in this application (check all that apply):		*Ethics Review and Approval Status (check all that apply and indicate date where applicable):			
		Application To Be Submitted	Applied, Review Pending	Reviewed	Approved
<input type="checkbox"/>	Baycrest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Bloorview Kids Rehab	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Centre for Addiction and Mental Health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Hospital for Sick Children	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Mount Sinai Hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	St. Michael's Hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Sunnybrook and Women's College Health Sciences Centre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Toronto Rehabilitation Institute	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	University Health Network	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	University of Toronto	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other (e.g. Hamilton Health Sciences REB, University of Western Ontario Health Sciences REB, other GTA hospitals):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Include all relevant correspondence related to ethics and scientific review (e.g. REB review letter, replies, approval letter).**

**8. CLINICAL TRIAL APPLICATION**

This section must be completed for clinical trials only. See TAHSN guidelines for Health Canada's definition of a clinical trial.

Not applicable  If not applicable proceed to Question 10.

**8A. If this study involves any of the following, check all that apply:**

<input type="checkbox"/> Investigational drug(s) - drug name(s): _____ ,
<input type="checkbox"/> Approved drug for new indication, dosage, or formulation (e.g. new patient population) - drug name(s): _____ ,

<input type="checkbox"/>	Investigational biologics – name(s) of biologics: _____ ,
<input type="checkbox"/>	Investigational natural health products (NHP) – NHP name(s): _____ ,
<input type="checkbox"/>	Investigational medical devices – device name(s): _____ ,

**8B. If this study involves submission to Health Canada under the Food and Drug Act: Is Health Canada “No objection letter” or regulatory authorization attached?**  Yes  No  
**If No, when is it expected?**

**8C. Provide the FDA IND number (drug studies) or PMA number (device studies):**

**FDA IND #:**  Pending

**PMA #:**  Pending

Not Applicable

**Note:** final approval will not be granted until the appropriate regulatory approval has been received.

**9. CLINICAL TRIAL REGISTRATION**

The International Committee of Medical Journal Editors (ICJME) has indicated that clinical trials will not be published without the registration of that trial prior to subject enrolment. A clinical trial is defined by ICJME as, "Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. This definition includes drugs, surgical procedures, devices, behavioural treatments, process-of-case changes and the like. A trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration."

**Given the above definition, indicate whether this trial will be registered (e.g., [www.clinicaltrials.gov](http://www.clinicaltrials.gov), [www.controlled-trials.com/isrctn/](http://www.controlled-trials.com/isrctn/)).**  Yes  No  Not Applicable

**If Yes, provide registration site:**

**SECTION II: STUDY SUMMARY**

**Note:** Responses to this section are not a substitute for the full protocol.

**10. ABSTRACT**

**Must be summary of study suitable for lay audience.**

(Max ¼ page)

**11. RATIONALE AND HYPOTHESIS/RESEARCH QUESTION**

**11A. Indicate the rationale for this study.**

(Max ¼ page)

**11B. Indicate the hypothesis for this study or research question.**

(Max ¼ page)

**11C. Indicate the significance of the study (i.e. the overall anticipated public and/or scientific benefit).**

(Max ¼ page)

**12. STUDY DESIGN**

Many of these questions apply to clinical research studies. If any of the items are not applicable to your study, indicate N/A.

**12A. Describe the design and methodology (e.g. pre/post design, pilot, study visits, procedures, study intervention).**

(Max ½ page)

**12B. Describe the primary outcome measures/goals of the study.**

(Max ¼ page)

**12C. List any criteria for premature withdrawal of a subject from the study for safety concerns.**

Not Applicable

(Max ¼ page)

**12D. Is a placebo used in this study?**  Yes  No

**If Yes, explain how this is this justified (e.g. no alternative standard treatment available). Include any provisions in place to reduce risks to subjects assigned to placebo (e.g., increased monitoring, rescue medication).**

(Max ¼ page)

**12E. Does this study involve deception or intentional lack of disclosure?**  Yes  No

**If Yes, justify and indicate how subjects will be debriefed.**

(Max ¼ page)

**12F. Will the subject be withdrawn from or denied usual therapy for any condition in order to participate in the study or be subject to other restrictions during the study?**  Yes  No

(This would include medications that are prohibited or restricted in order to be eligible for the study or that may be prohibited or restricted during the course of the study.)

**If Yes, explain.**

(Max ¼ page)

**13. SUBJECT/CONTROLS****13A. Indicate the main inclusion/exclusion criteria.**

(Max ¼ page)

i) Indicate the age range of eligible subjects:

**13B. If applicable, indicate the rationale for control group(s).**

(Max ¼ page)

**13C.**

**Total study enrollment:**

**Number of subjects to be enrolled at this institution:**

**Indicate the time period for enrollment:**

**Approximate size of eligible population from institution/practice:**

**13D. Is sample size justified in the protocol?**  Yes  No

**If Yes, indicate protocol page:**

**If No, provide sample size justification.**

(Max ¼ page)

#### **14. STUDY INTERVENTIONS OR PROCEDURES**

Not Applicable  (e.g. observational studies). If not applicable, go directly to 15. DATA ANALYSIS

**14A. Document the usual standard of care at this institution for this population.**

Not Applicable

(Max ¼ page)

**14B. Indicate what procedures are to be carried out in the study, that are not considered part of the diagnostic, therapeutic “routine” or indicate how standard of care is altered. Attach a copy of all non-standardized instruments (e.g., questionnaires, rating scales).**

(Max ¼ page)

**14C. Indicate the additional risks associated with the study as compared to usual standard of care. Do not refer to other sections of this form.**

(Max ½ page)

**14D. Indicate duration of study visits and extra time commitment (length, number, and frequency of test sessions) for study participation.**

(Max ¼ page)

#### **15. DATA ANALYSIS**

**Briefly explain what methods will be used to analyze study data.**

References to protocol for this question are acceptable. Indicate applicable page(s) of protocol.

(Max ¼ page)

**SECTION III: ETHICAL ISSUES**

**16. RECRUITMENT AND CONSENT**

Not Applicable

**Note:** Any document to be viewed by the subject (e.g., recruitment posters/letters, consent/assent forms, information sheets) must be included with your submission.

**16A. Indicate what tools will be used to identify potential subjects for recruitment into the study.**

<input type="checkbox"/> Permanent health record/clinical chart (specify source):
<input type="checkbox"/> Existing database (specify):
o Does the Principal Investigator maintain the database? <input type="checkbox"/> Yes <input type="checkbox"/> No
o If No, identify the entity that maintains the database:
Note: The creation and maintenance of a database for research purposes is a research activity that may require a separate REB application. Consult your institutional REB.
<input type="checkbox"/> Advertisements, including web based recruitment tools (attach)
<input type="checkbox"/> Other (specify):

**16B. Indicate who will identify potential study subjects**

- Investigator/study personnel
- Other healthcare professional (e.g. non-study personnel)
- Self-referral (e.g. response to advertisement)

**i) Identify all persons who will be reviewing health records/identifying information (for recruitment purposes).**

1	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
2	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
3	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
4	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
5	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:

**ii) List the identifying information that will be collected, used, or disclosed from the records during the course of the proposed recruitment activities.**

<input type="checkbox"/> Name	<input type="checkbox"/> Images (e.g., photographic, x-ray, MRI scans)
<input type="checkbox"/> Address	<input type="checkbox"/> Social Insurance Number
<input type="checkbox"/> Telephone Numbers	<input type="checkbox"/> Medical Record Number
<input type="checkbox"/> Email Address	<input type="checkbox"/> Date of Birth
<input type="checkbox"/> Health Card Number	<input type="checkbox"/> Health Information: (e.g., relating to inclusion /exclusion criteria, medications)

Other information (specify):

**iii) Describe the security measures that will be taken to protect the confidentiality of this information.**

(Max ¼ page)

**iv) Indicate what will happen to this information at the completion of the recruitment process.**

(Max ¼ page)

**16C. Indicate who will make initial contact with potential subjects or authorized third party, whether they are already known to the subject or authorized third party, and how contact will be made (e.g., in person, phone, letter, e-mail, website). Attach a copy of the script or any written materials if applicable.**

(Max ¼ page)

**16D. Describe the consent process and who will obtain consent (e.g. will consent be written, oral, telephone (include script)). If the study population requires special consent considerations (e.g., child, incompetent adult, unable to communicate), refer to 16E.**

(Max ¼ page)

**i) Indicate if there is a relationship between the subjects and either of the following:**

Person obtaining consent  Yes  No  
Investigator  Yes  No

**ii) If Yes, explain the nature of the relationship (e.g., physician, employer) and what steps will be taken to avoid the perception of undue influence.**

(Max ¼ page)

**iii) Indicate how much time will be given to subjects to review the information before being asked to give consent.**

(Max ¼ page)

**16E. Indicate if the research will involve any of the following:**

**i) Special Considerations (check all that apply):**

- |   |   |
|---|---|
| <input type="checkbox"/> Women of child bearing potential | <input type="checkbox"/> Genetic research         |
| <input type="checkbox"/> Pregnant women                   | <input type="checkbox"/> Tissue samples           |
| <input type="checkbox"/> Healthy volunteers               | <input type="checkbox"/> Fetal tissue or placenta |
| <input type="checkbox"/> Students                         | <input type="checkbox"/> Prisoners                |
| <input type="checkbox"/> Staff                            | <input type="checkbox"/> None of the above        |

**ii) Capacity/Competency (check all that apply):**

- Children less than 16 years of age
- Emergency patients
- Individuals temporarily unable to provide an informed consent
- Marginally incompetent subjects



- Incompetent subjects
- None of the above

**Describe how capacity will be assessed for any individuals in 16Eii.**

(Max ¼ page)

**If subjects are incapable of providing consent, provide information on how substitute decision makers will be identified.**

(Max ¼ page)

**When inability to provide an informed consent is expected to be temporary, describe what procedures will be used to regularly assess capacity and to obtain consent if the individual later becomes capable of providing consent.**

(Max ¼ page)

**iii) Communication Difficulties (check all that apply):**

- Individuals who may require translation
- Individuals who are illiterate
- Subjects unable to communicate
- None of the above

**Provide an explanation of what procedures will be used to address any communication difficulties (e.g., the use of translated forms, translator, impartial witness).**

(Max ¼ page)

**16F. If potential subjects might be approached for recruitment in other studies, indicate the steps that will be taken to minimize the number of times that this will occur.**

(Max ¼ page)

**17. RISK/BENEFIT ESTIMATES**

**17A. Potential Benefits to Subjects**

No direct benefits anticipated

**List anticipated benefits to the subject, if any.**

(Max ¼ page)

**17B. Potential Harms (injury, discomfort and inconvenience) to subject (including psychological factors).**

No known risks

**i) List the known risks of study intervention(s) including approximate rates of occurrence, severity and rates of reversibility.**

(Max ¾ page)

**ii) List the risks of any tests, procedures or other protocol-mandated activities that are conducted for research purposes only, including approximate rates of occurrence, severity and reversibility.**

(Max ¾ page)

**iii) For studies involving placebo, washout, or withholding treatment, list any risks related to absence of treatment.**

Not Applicable

(Max ¾ page)

**iv) Include a summary of the data regarding reproductive risks such as teratogenicity or embryotoxicity of the study drug, any risk with breastfeeding, or risk to men regarding conception.**

Risks unknown

(Max ¼ page)

**v) Indicate whether participation in this study affects alternatives for future care.**

Yes  No

**If Yes, explain.**

(Max ¼ page)

**18. PAYMENTS**

Not Applicable

**18A. Indicate what payment(s) will be provided to subjects or substitute decision makers, if applicable.**

<input type="checkbox"/> Reimbursement for expenses incurred as a result of research Amount: _____ Specify (e.g., travel, meals): _____
<input type="checkbox"/> Gifts for participation Value: _____
<input type="checkbox"/> Compensation for time Amount: _____ Provide justification if compensation for time will be provided. (Max 1/4 page)
<input type="checkbox"/> Other forms of compensation: _____

**19. MONITORING**

**19A. Indicate if there is a plan for monitoring of the study (e.g. sponsor initiated site visits)**

Yes  No  Not Applicable

**If YES, describe.**

(Max ¼ page)

**19B. Indicate if an interim analysis is planned.**  Yes  No  Not Applicable

**If Yes, describe briefly.**

(Max ¼ page)

**19C. Indicate if there is a steering committee.**  Yes  No  Not Applicable

**If Yes, provide a copy of the terms of reference (mandate) of the steering committee.**

**19D. Indicate if there is a data and safety monitoring board (DSMB).**

Yes  No  Not Applicable

**If Yes, forward a copy of the DSMB charter when available or provide a description of the DSMB, including its purpose, membership, relationship to the sponsor, and whether the committee will review unblinded study data etc. Refer to the protocol as needed.**

(Max ¼ page)

**If No, justify and explain what alternative arrangements are in place to monitor the safety data and how the overall risk/benefit information will be communicated to the REB.**

(Max ¼ page)

**20. POTENTIAL CONFLICTS OF INTEREST**

If any of the conflicts listed below apply to any of the Investigators involved in the research study or any member of their immediate family, append a letter to the Chair of the REB detailing these activities and how they will be managed. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. Conflict of interest may also arise with regard to the disclosure of personal health information.

<input type="checkbox"/> Function as an advisor, employee, officer, director or consultant for the study sponsor
<input type="checkbox"/> Have direct or indirect financial interest in the drug, device or technology employed in this research study (including patents or stocks)
<input type="checkbox"/> Receive an honorarium or other personal benefits from the sponsor (apart from fees for service)
<input type="checkbox"/> Receive direct or indirect financial benefit from the disclosure of personal health information
<input type="checkbox"/> Other
<input type="checkbox"/> None of the above

**21. PUBLICATION/DISSEMINATION OF RESULTS**

**Indicate how the results will be communicated to subjects and other stakeholders (e.g., advocacy groups, scientific community).**

<input type="checkbox"/> Individual debriefing at end of test session	<input type="checkbox"/> Publication
<input type="checkbox"/> Group debriefing	<input type="checkbox"/> Other (specify):
<input type="checkbox"/> Letter of appreciation at end of study	<input type="checkbox"/> No Plan

**If no plan is in place, provide justification.**

Not Applicable

(Max ¼ page)

**SECTION IV: PRIVACY AND CONFIDENTIALITY**

**22. COLLECTION USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION**

Investigators should comply with the duties set out for researchers in the Personal Health Information Protection ACT (PHIPA – effective in Ontario Nov. 1, 2004) and with the privacy and confidentiality and consent guidelines outlined in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans.

**22A. List all personal health information and personal identifiers (e.g. name, DOB) required to be collected. For all non-clinical trials, attach data collection forms.**

(Max ¼ page)

**22B. Identify all potential sources of this information.**

(Max ¼ page)

**22C. Indicate how study subjects will be identified on data collection forms (e.g. study number, initials).**

(Max ¼ page)

**22D. Indicate how data will be stored.**

<input type="checkbox"/> Computerized files (specify): Server <input type="checkbox"/> Desktop <input type="checkbox"/> Laptop <input type="checkbox"/>
<input type="checkbox"/> Audio recordings
<input type="checkbox"/> Hard copy
<input type="checkbox"/> Videotape
<input type="checkbox"/> Other (e.g. PDA):

**i) Describe the safeguards to protect the confidentiality and security of the data, including any physical and technical safeguards (e.g. data will be stored in a locked and secure area, the data will be stored on a secure server that is password protected)**

(Max ¼ page)

**ii) Indicate who will have access to these data in the future.**

(Max ¼ page)

**22E. Indicate if any information that could potentially identify study subjects will be disclosed outside of the institution (e.g., names, initials, DOB, OHIP #).**

Yes  No

**If Yes, justify and describe how this information will be transferred and any security measures to be used (e.g., anonymized data, secure network upload or download).**

(Max ¼ page)

**22F. If personal health information is to be linked to other databases (e.g., health registries, statistics Canada information) provide the following details:**

Not Applicable

**i) Describe the data to which the personal health information will be linked.**

(Max ¼ page)

**ii) Explain how the linkages will be made.**

(Max ¼ page)

**iii) Explain why these linkages are required.**

(Max ¼ page)

**22G. Indicate how long the personal health information will remain identifiable and explain why.**

Not Applicable

(Max ¼ page)

**22H. Identify all persons (in addition to those listed in Q. 16Bi) that will have access to the personal health information, their roles in the study, their reason for access, and related qualifications.**

1	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
2	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
3	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
4	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
5	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:

**22I. Explain why the research cannot reasonably be accomplished without using personal health information.**

(Max ¼ page)

**22J. If personal health information will be collected, used or disclosed without consent from the individuals to whom the information relates, explain why obtaining explicit consent would be impractical.**

(Max ¼ page)

**22K. Describe any harms or benefits that could arise if personal health information was inappropriately released (e.g., embarrassment, refusal of employment or insurance coverage, stigmatization of individuals / groups) and how any consequences would be addressed.**

(Max ¼ page)

**22L. Describe how and when the personal health information will be disposed of or returned to the health information custodian.**

(Max ¼ page)

**SECTION V: FUNDING AND CONTRACTS**

**23. BUDGET**

No budget required

Attach an itemized study budget (applies to all full board and expedited review studies). The budget should reflect all costs at this institution.

Indicate whether the funding is sufficient to cover all study costs.  Yes  No

If No, explain how the shortfall will be made up.

(Max ¼ page)

Indicate if any investigator will receive direct personal payments from the budget.  Yes  No

If Yes, describe what these payments are for and the amount.

(Max ¼ page)

**24. AGREEMENTS**

**24A. Contract/Research Agreement**

Indicate whether there is a contract/research agreement involved  Yes  No

If Yes, provide name of sponsor/agency and contact information (address, phone number and contact name for billing purposes):

Provide name of the contract research organization and contact information (address, phone number and contact name for billing purposes): Not applicable

**24B. Indicate whether the contract/research agreement has been submitted for review and signing. (See institution specific instruction page)  Yes  No**

**24C. Indicate if there is external (non-institutional) liability insurance.  Yes  No**

ii) Indicate who will cover reasonable out-of pocket expenses to ensure that immediate medical care is provided if a subject suffers an injury as a result of participation in the study.

Sponsor

Institution

Other (specify):

#### 24D. Publication Agreements

i) Indicate if there is an agreement between the Investigator and the sponsor regarding the use, publication or disposal of the data.  Yes  No  Pending

ii) If Yes, Indicate whether the funding agency or sponsoring company places any restrictions on publication of findings or reporting interim results.  Yes  No  Pending

iii) If Yes, explain any restrictions.

(Max ¼ page)

#### 25. MATERIAL TRANSFER AGREEMENT

Indicate if there is a material transfer agreement (MTA) involving human material for this study. This refers to an agreement for transfer of biological materials (e.g. tissues, cell lines) from the institution to another institution or entity.  Yes  No

If Yes, attach a copy of the agreement.

#### 26. INFORMATION SHARING

Indicate if there is an information sharing agreement.  Yes  No

If Yes, attach a copy of the agreement.

Principal Investigator: REB #:
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**Toronto Academic Health Sciences Network (TAHSN)  
MSH Instructions and Study Impact Signature Page (Appendix 1)**

Some administrative details surrounding research protocols differ throughout the TAHSN hospitals. This form is a Mount Sinai Hospital supplement to the TAHSN application form. Please consult the MSH TAHSN guidelines for details of study impact by department.

**STUDY IMPACT**

Does the study impact on other hospital departments or services? Yes  No

If yes, provide signature to indicate protocol has been submitted to appropriate department.

Note that the Principal Investigator is responsible for all successful negotiations with departments.

Departments/Committees	Impact	Departmental/Divisional Signature
Pharmacy Bill Wilson ext:5016	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Biomedical Engineering Robert Wilson ext: 5973	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Medical Imaging Debbie Havill ext:16-4310	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Nursing ext: 2352 Tracy Kitch	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Pathology & Lab Medicine Maria Mendes ext: 4479 Azar Azad ext: 8545	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Microbiology Tony Mazzulli ext:4695	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Cardiology Robyn Joliffe ext: 8584	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Respiratory Therapy Lynda Hutchens-Richmond ext: 8238	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Peroperative Services Sharon Ball exr0t: 2630	Yes <input type="checkbox"/> No <input type="checkbox"/>	